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MEMORANDUM

SUBJECT: Evaluation of Pollinator Data and Recommendations for Updating
Honeybee Label Language on BAS 556 SC Fungicide (Pyraclostrobin and
Metconazole)

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The Environmental Fate and Effects Division (EFED) has completed the review of an acute oral and contact honeybee study (MRID 49525001) that was submitted by BASF Corporation in support of updating the honeybee precautionary label language on BAS 556 SC Fungicide (EPA Reg Number 7969-291). This memo presents: 1) EFED's conclusion from the study review; and 2) a Tier 1 and Tier 2 pollinator analysis to determine if changes to the honeybee precautionary statements on the current label are warranted. In summary, MRID 49525001 is classified as "acceptable" and demonstrates that pyraclostrobin and metconazole are "practically non-toxic" to honeybees on an acute contact basis and "moderately toxic" to honeybees on an acute oral basis. **Based on the pollinator analysis for acute effects to adult honeybees, EFED agrees with the registrant's premise that the removal of the honeybee precautionary language on the BAS 556 SC Fungicide label is supported by the submitted data.**

Review of Honeybee Acute Contact and Oral Toxicity Study

EFED has reviewed the honeybee acute contact and oral toxicity study that was conducted with BAS 556 02 F, a formulation with two active ingredients – pyraclostrobin and metconazole. The study is classified as “acceptable.” Endpoints are presented both in terms of pyraclostrobin and metconazole and show that both chemicals are “practically non-toxic” to honeybees on an acute contact basis and “moderately toxic” to honeybees on an acute oral basis. Study details are presented in Table 1.

Table 1. Details for the Acute Honeybee Pyraclostrobin-Metconazole Study

Study Type	Organism	MRID	Study Citation	Study Classification	Summary
Acute oral and contact toxicity to honeybee 850.3020 OECD 213 TEP (13.34 % pyraclostrobin; 5.03% metconazole)	Honeybee (<i>Apis mellifera</i>)	49525001	Franke, M. 2014. Acute toxicity of BAS 556 02 F to the honeybee <i>Apis mellifera</i> L. under laboratory conditions. Laboratory Report ID: 14 10 48 038 B. Study performed by BioChem agrar Labor for biologische und chemische Analytik GmbH, Gerichshain, Germany. Sponsored by BASF SE, Ludwigshafen, Germany.	Acceptable	<u>Acute Oral Toxicity</u> LD ₅₀ = 76.6 µg formulation/bee LD ₅₀ = 3.85 µg metconazole/bee LD ₅₀ = 10.2 µg pyraclostrobin/bee Sublethal effects: impaired locomotion at the 4-hour observation interval; however, this effect was only transient <u>Acute Contact Toxicity</u> LD ₅₀ > 532.5 µg formulation/bee LD ₅₀ > 26.8 µg metconazole/bee LD ₅₀ > 71.0 µg pyraclostrobin/bee Sublethal effects: impaired locomotion at the 4-hour observation interval; however this effects was only transient

Pollinator Risk Assessment for BAS 556 SC

BASF has proposed the removal of the honeybee precautionary language from BAS 556 SC Fungicide. Currently the label reads: “This product is toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product if bees are visiting the treatment area.” BASF claims that the recently submitted acute honeybee data show that the contact toxicity of pyraclostrobin and metconazole is “practically non-toxic” to honeybees. However, the oral toxicity classification for both chemicals is “moderately toxic;” consequently, honeybee warnings are still justified.

As a next step, EFED performed a Tier 1 analysis, according to the Pollinator Risk Assessment Framework (USEPA 2014). The toxicity values from the BAS 556 SC formulation (see Table 1) were used in the analysis. Sublethal effects included impaired locomotion at dose levels of 66.6, 133.1, and 266.2 µg formulation/bee for oral exposures and 133.1, 266.2 and 532.5 µg formulation/bee for contact exposures. Sublethal effects were only observed at the 4-hour observation period. By 24 hours, the bees appeared normal and healthy, suggesting that the impaired locomotion was a transitory effect and would not likely translate into whole colony effects.

The acute environmental exposure concentrations (EECs) from a foliar spray of BAS 556 SC are based on a single maximum application rate of 0.19 lb pyraclostrobin/A and 0.07 lb metconazole/A. Repeat applications are permitted, but the honeybee EECs are based solely on the single maximum application rate. EECs for adult honeybees were calculated as follows (Table 2) (USEPA 2014):

Table 2. Adult Honeybee EECs for BAS 556 SC

Exposure Route	EEC Equation	EEC
<i>Pyraclostrobin (application rate of 0.19 lb ai/A)</i>		
Acute Contact	(single app rate) x (2.7 µg ai/bee)	0.51 µg ai/bee
Acute Dietary	(single app rate) x (110 µg ai/g) x (0.292 g/day)	6.10 µg ai/bee
<i>Metconazole (application rate of 0.07 lb ai/A)</i>		
Acute Contact	(single app rate) x (2.7 µg ai/bee)	0.19 µg ai/bee
Acute Dietary	(single app rate) x (110 µg ai/g) x (0.292 g/day)	2.25 µg ai/bee

EECs were not calculated for larval honeybees or chronic exposures to adults because corresponding toxicity data are not available.

Risk quotients (RQs) were calculated by dividing the EEC by the toxicity value. If the resulting RQ is above the LOC of 0.4 for honeybees, risk concerns are flagged as possible. For the acute contact data, the endpoints are non-definitive (i.e., “greater than” values), and an RQ cannot be calculated. As an alternative, the toxicity value is compared directly to the EEC. For BAS 556 SC, the acute contact toxicity values were much greater than the EECs; consequently, risk concerns based on a contact exposure pathway are not expected. The RQs for the acute dietary exposure route are above the LOC of 0.4, indicating potential risk concerns for adult honeybees (Table 3).

Table 3. Risk Quotients for Adult Honeybees Exposed to BAS 556 SC

Exposure Route	Pyraclostrobin	Metconazole
Acute Contact	0.51 µg ai/bee is much less than the LD ₅₀ of 71.0 µg ai/bee	0.19 µg ai/bee is much less than the LD ₅₀ of 26.8 µg ai/bee
Acute Dietary	0.59*	0.58*
*Exceeds the honeybee LOC of 0.4.		

Acute dietary risk to adult honeybees was further refined by proceeding to a Tier 2 assessment that incorporates measured pollen and nectar residue values. Pollen and nectar data are available from two studies (MRIDs 49459604, 49459605) with BAS 556 03 (also a pyraclostrobin and metconazole formulation). A single foliar application was made to either winter oilseed rape or sunflower at an application rate of 1.27 lb

pyraclostrobin/A and 0.71 lb metconazole/A. Pollen and nectar were collected directly from the treated crops within 24 hours of the application. There are uncertainties associated with residue studies such as the variability of environmental degradation, crop differences, application rates, and sampling timing. However, because the application rate was much higher than the labeled rate on BAS 556 SC and residues were measured within 24 hours after application, there is confidence that the residue values are protective for this analysis. Table 4 presents the highest measured residues for each crop.

Table 4. Pyraclostrobin and Metconazole Residues in Pollen and Nectar

Crop	Pollen	Nectar
<i>Pyraclostrobin</i>		
Sunflower	17.00 mg/kg (4.96 µg/bee) ¹	0.53 mg/kg (0.15 µg/bee) ¹
Oilseed rape	7.787 mg/kg (2.27 µg/bee)	0.231 mg/kg (0.07 µg/bee)
<i>Metconazole</i>		
Sunflower	11.00 mg/kg (3.21 µg/bee)	0.33 mg/kg (0.10 µg/bee)
Oilseed rape	4.582 mg/kg (1.34 µg/bee)	0.305 mg/kg (0.09 µg/bee)
¹ Conversion made by multiplying residue concentration (EEC) by the food consumption rate of 0.292 g/day		

Oral consumption rates of pollen and nectar are dependent on the life stage of the honeybee [guttation water is not considered here because exposures are expected to be higher for other food items (*i.e.*, pollen and nectar) (USEPA 2014)]. Table 5 depicts the expected food consumption rate for different adult honeybees. To calculate risk quotients, the estimated dose per day for each food item is divided by the oral toxicity value. Risk quotients were calculated using the oral dose toxicity information from the BAS 556 02 data because it is directly relevant to the BAS 556 SC label. None of the RQs exceeded the LOC of 0.4 for honeybees (Table 6).

Table 5. Estimated Consumption Rates of Pollen, Nectar and Royal Jelly by Adult Honeybees

Life Stage	Caste	Daily consumption rate (mg/day)				
		Average Age (in days)	Brood food / royal jelly	Nectar**	Pollen***	Total food
Adult	Worker (cell cleaning and capping)	0-10	none	60	5.2	65
	Worker (brood and queen tending, nurse bees)	6-17	none	140	8.85	149
	Worker (comb building, cleaning and food handling)	11-18	none	60	1.7	62
	Worker (foraging for pollen)	>18	none	43.5	0.041	44
	Worker (foraging for nectar)	>18	none	292	0.041	292
	Worker (maintenance of hive in winter)	0-90	none	29	2	31
	Drone	>10	none	235	0.0002	235
	Queen	0+	unknown	unknown	None	unknown

Source: USEPA 2014 Pollinator Risk Assessment Framework;
NA = not applicable
*From Winston 1987
**From Rortais *et al.* 2005. Assumes that average sugar content of nectar is 30%.
*** From Crailsheim *et al.* (1992, 1993).

Table 6. Refined Acute Oral Risk Quotients for Adult Honeybees Using Maximum Reported Concentrations in Pollen and Nectar

Life Stage	Cast/Task	Average Age (d)	Total food Consumption (g/d)	Estimated Oral Dose (ug ai/bee/d) ¹		Acute RQ ²	
				Pyraclostrobin	Metconazole	Pyraclostrobin	Metconazole
Adult	Worker (cell cleaning and capping)	0-10	0.065	0.12	0.08	0.01	0.02
	Worker (brood and queen tending, nurse bees)	6-17	0.149	0.23	0.14	0.02	0.04
	Worker (comb building, cleaning and food handling)	11-18	0.062	0.06	0.04	0.01	0.01
	Worker (foraging for pollen)	>18	0.0435	0.03	0.02	<0.01	0.01
	Worker (foraging for nectar)	>18	0.292	0.15	0.10	0.01	0.03
	Worker (maintenance of hive in winter)	0-90	0.031	0.05	0.03	<0.01	0.01
	Drone	>10	0.235	0.12	0.08	0.01	0.02
	Queen	0+	unknown	unknown		unknown	

¹ Oral dose determined using maximum concentrations of pyraclostrobin in pollen (17.00 mg/kg) and nectar (0.53 mg/kg), and metconazole in pollen (11.00 mg/kg) and nectar (0.33 mg/kg) reported in Table 4 multiplied by the estimated cast-specific consumption rate. The dose is reflective of the percent pollen and nectar that adult honeybees typically consume in a day (*i.e.*, for nectar, the maximum concentration found in nectar is multiplied by the nectar consumption rate. The same is done for pollen and these are then added together for the total pyraclostrobin or metconazole consumption rate).

² Acute RQs determined as the ratio of oral dose to the acute LD₅₀ for pyraclostrobin (10.2 µg ai/bee) and metconazole (3.85 µg ai/bee).

Conclusions

Given that all of the RQs are below the LOC of 0.4 for honeybees, no risk concerns are expected for acute dietary exposures to adult honeybees. Combined with the results of the Tier 1 analysis for the contact exposure route, acute risk concerns are not anticipated for adult honeybees. There remains uncertainty about risk concerns for chronic exposures to adults and acute/chronic exposures to larvae. **Based on the current analysis, acute risks to honeybees are not expected to exceed the risk threshold of concern. Consequently, the analysis supports removing the honeybee precautionary language from the label at this time. The label language may be re-evaluated if larval and/or chronic adult data indicate the potential for risk concerns to bees.**

References

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